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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,671	08/27/2001	David W. LaFleur	PZ022P1C2	3552
22195	7590	06/10/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			SWITZER, JULIET CAROLINE	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/938,671

Applicant(s)

LAFLEUR ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11, 13, 15, 17-20, 22 and 24-51 is/are pending in the application.
- 4a) Of the above claim(s) 11, 13, 15, 17-20, 22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

1. This action is written in response to applicant's correspondence submitted 4/12/04. Claims 18, 34-36, and 38-43 have been amended, claims 1-10, 12, 14, 16, 21, and 23 have been canceled. Claims 11, 13, 15, 17-20, 22, and 24 are pending and withdrawn from consideration as being drawn to non-elected subject matter. Claims 25-51 are under examination herein. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is non-final.**
2. The examiner handling this application has changed. Please address future correspondence to Examiner Juliet Switzer, Art Unit 1634.
3. The objections to claims 34-36 and 38-39 are moot in view of the amendment to the claims.
4. Applicant's point regarding the incomplete nature of the 101/112 1<sup>st</sup> lack of utility rejection in the previous office action has been considered and is persuasive. A complete rejection is included in this office action.

### ***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 25-51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The rejected include claims drawn to isolated nucleic acid molecules that encode SEQ ID NO: 83 or portions of SEQ ID NO: 83, as well as constructs (vectors, host cells) which contain these nucleic acids. Additionally, the rejected claims include claims to the polynucleotide encoding the amino acid sequence which is encoded by the HMADS41 cDNA clone. The claims also include polynucleotides 95% or more identical to these recited polynucleotides.

The instant specification teaches in table 1, p. 90, that the HMADS41 cDNA clone is contained within ATCC deposit 209563, and comprises SEQ ID NO: 38, which encodes SEQ ID NO: 83. The table identifies this gene as "Gene No. 28." Turning to the text of the specification, the specification teaches that Gene No. 28 is primarily expressed in a variety of tissues, including pulmonary, endothelial, umbilical cord and fetal tissues (p. 68, lines 25-26). The specification concludes, therefore, that these polynucleotides are useful for differential identification of tissues or cell types, and are also useful for diagnosis of asthma, pulmonary edema, artherosclerosis, restenosis, stroke, thrombosis, and hypertension.

The specification further teaches that any of polynucleotides of the present invention are useful for chromosome identification, in preparing PCR primers, and in methods which map the polynucleotide to a chromosome, utilize the mapped chromosome in linkage analysis, establish coinheritance of the polynucleotide, and then to study affected and unaffected individuals looking for differences in gene structure and/or expression (p. 110-112 of the specification). The specification further teaches that the genes can be used to inhibit expression via antisense therapy or in gene therapy (p. 112), and that the polynucleotides are useful for forensics to identify

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individuals (p. 113) or as molecular weight markers (p. 114). The specification teaches that the polynucleotides of the claimed invention can be tested for biological activity and may be associated with diseases associated with a biological activity. If so, the polynucleotides could be used to treat diseases (p. 116). The potential biological activities contemplated in the specification include immune activity, the inhibition of proliferation, to regenerate or proliferate cells, to attract or mobilize cells (chemotaxis), binding activity, increasing or decreasing the proliferation of embryonic stem cells, to modulate mammalian characteristics (body height, for example), to change a mammal's mental state, or as a food additive or preservative (to increase or decrease storage capabilities, for example).

None of the utilities asserted by applicant in the specification are specific and substantial with regard to the claimed invention, as further experimentation would be required to reasonably confirm a real world utility for the any of the asserted methods. The specification does not disclose an association between the instantly claimed polynucleotides, for example, and a disease or phenotype. For example, at page 25 of the specification, it is asserted that because nucleic acids encoding SEQ ID NO: 83 are expressed in a variety of tissues, the nucleic acid can therefore be used in the diagnosis and/or treatment of a wide variety of diseases and conditions, such as asthma, pulmonary adema, atherosclerosis, restenosis, stroke, thrombosis and hypertension. However, the specification does not provide any guidance as to these utilities, for example, how are the claimed molecules diagnostic of any or all of these diseases or under what conditions they might be used to treat these diseases. These diseases have a wide range of symptomologies and etiologies, and the specification does not establish a connection between nucleic acids which encode instant SEQ ID NO: 83 and any one or all of these diseases. While

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these uses in themselves could be considered “real world” uses, they are not substantial with regard to the claimed invention because it would require further experimentation to reasonably confirm any one of the suggested utilities apply to nucleic acids which encode SEQ ID NO: 83. Each of the recited possible utilities are in effect an invitation to further analyze the polynucleotides which encode SEQ ID NO: 83 to determine if in fact a real world use exists for the claimed molecules. Utilities such as for the identification of primers and mapping chromosomes are further non-specific utilities which could be applied to any nucleic acid. There is no specific, substantial and credible well known utility established for nucleic acids encoding instant SEQ ID NO: 83, as these were known in the prior art at the time the invention was made.

Claims 25-51 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112, Written Description***

8. Claims 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, are 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims 33-39 are drawn to isolated polynucleotides having 95% identity to polynucleotides that encode SEQ ID NO: 83 or portions of SEQ ID NO: 83. Claims 40-42 comprise fragments of 150 contiguous nucleotides of polynucleotides that encode SEQ ID NO: 83. This large genus is represented in the specification by one example, polynucleotides which encode SEQ ID NO: 83 and polynucleotides that consists of fragments of the polynucleotides

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that encode SEQ ID NO: 83. The claims, on the other hand encompass variations of SEQ ID NO: 83 that are not disclosed and could include splice variants, allelic variants, and functional variants. There is no functional language in the claim to further define the encompassed polynucleotides, and the specification is not clear as to what function the polypeptide encoded by the claimed polynucleotides encompass. Thus, applicant has express possession of a limited number of examples in a genus which comprises hundreds of millions of different possibilities.

With regard to claims 40-42, this rejection could be overcome by indicating that the claimed nucleic acids CONSIST of fragments of the nucleic acid encoding nucleotides 1088 of SEQ ID NO: 83.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 33-39 include modifications by permitted by the % identity language for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acids encoding the disclosed amino acid sequence of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

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In the application at the time of filing, there is no record or description which would demonstrate possession of any nucleic acids modified by addition, insertion, deletion, substitution or inversion with the disclosed sequences but encoding one or more amino acid differences such that a different amino acid sequence is encoded retains the function or activity of instant SEQ ID NO: 83.

### **Response to Remarks**

On page 12 of the response, Applicants point to portions of the specification to support the utility of the claimed invention. However, for the reasons discussed in the rejection, these remarks are not persuasive. The rejection is maintained.

The 102 rejections in view of Sommer *et al.* are withdrawn in view of Applicants' remarks on p. 13-15 of the response. Namely, the rejection is withdrawn because the nucleic acid taught by Sommer *et al.* is not 95% identical to a polynucleotide encoding any one of choices (a), (b), or (c) as required by claim 33 or (a) and (b) as required by claim 37. The polynucleotide taught by Sommer *et al.* comprises a polynucleotide that is 95% identical to only a portion of the molecules recited in the claims and not to the entire molecule, as is intended and required by the claim. Likewise the 102 rejections in view of Jacobs *et al.* are withdrawn with respect to claims 33 and 37 for the same reason and in view of applicant's arguments on p. 16, second full paragraph of the response.

The 102 rejection in view of Jacobs *et al.* is also withdrawn as it was applied to claims 40-43 as Jacobs *et al.* do not meet the limitation of the claims which require that the claimed nucleic acid comprise a nucleic acid that comprise at least 150 contiguous nucleotides of the polynucleotide encoding the recited residues. Jacobs *et al.* teach their SEQ ID NO: 907.



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Nucleotides 22-473 of the nucleic acid taught by Jacobs *et al.* are identical to nucleotides 484-935 of instant SEQ ID NO: 38. Instant SEQ ID NO: 83 is encoded by nucleotides 267-534 of instant SEQ ID NO: 38, and thus, the sequence taught by Jacobs *et al.* does not comprise at least 150 contiguous nucleotides of the nucleic acid encoding the recited polypeptides.

No rejections in view of the prior art remain.

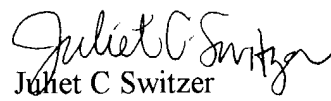
***Conclusion***

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached by calling (571) 272-0782.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

  
Juliet C Switzer  
Examiner  
Art Unit 1634

June 9, 2004